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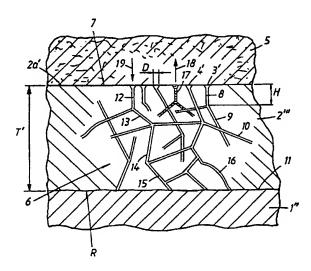
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(54) Title: LAYER ARRANGED ON IMPLANT FOR BONE OR TISSUE STRUCTURE, SUCH AN IMPLANT, AND A METHOD FOR APPLICATION OF THE LAYER



(57) Abstract: A layer (2''') is arranged on an implant (1'') for bone or tissue structure (5). The layer constitutes a boundary or barrier between the actual or unoxidized body (1'') of the implant and the structure for the purpose of increasing retention and has, in this context, a substantial thickness (T'). The layer is designed with a channel network (6) which gives the layer a substantial porosity. The channel network is designed with mouths (3', 4') which face towards the structure and whose respective cross-sectional diameters (D), at the surface (2a') of the layer facing towards the structure (5), are substantially less than the respective extents (e.g. H) of the channels in and down into the layer as seen from the said surface (2a').



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TITLE

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Layer arranged on implant for bone or tissue structure, such an implant, and a method for application of the layer.

#### TECHNICAL FIELD

The present invention relates to a layer which can be arranged on an implant for bone or tissue structure and which is intended to constitute a boundary or barrier between the body of the implant and the structure for the purpose of increasing retention context, in this a substantial which has, and thickness. The invention also relates to an implant with such a layer, and to a method for producing the said layer on the implant.

#### PRIOR ART

In connection with implants, it is already well known to arrange porous surfaces and oxide layers on 20 titanium-based material for various aims and purposes. Depending on the purpose, it has been proposed to use oxide layer thicknesses within a very wide range which extends from a few angstroms upwards. Reference may be made in purely general terms to various publications, 25 for example the article published by Dunn et al. "Gentamicin sulfate attachment and release from anodized TI-6A1-4V orthopedic materials" in "Journal of Biomedical Materials Research, Vol. 27, 895-900 (1993) and to the article "Formation and characterization of 30 anodic titanium oxide films containing Ca and P" by Hitoshi Ishizawa and Makoto Ogino in "Journal Biomedical Materials Research, Vol. 29, 65-72 (1995)". Reference may also be made in purely general terms to 35 the patent literature, for example to US Specifications 4,330,891 and 5,354,390 and to European Patent Application 95102381.1 (676179).

Considerable resources are being expended on research and development aimed at producing implants

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which can improve the process of incorporation of the implant in bone and tissue structures, for example in the jaw bone.

### DESCRIPTION OF THE INVENTION

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The present invention is based on the recognition that the oxide layer structure used in this context can have a decisive influence for improving implantation and incorporation processes. In the prior art there is no collective grasp of the actual build-up of the oxide layer structure and the need, at least in some circumstances, to be able to use very thick oxide layers. The aim of the invention is primarily to solve this problem.

15 In connection with application of implants in and tissue structures, it is important establish good corrosion resistance and, for example in connection with the use of hydrogen fluoride (HF), to avoid the occurrence of brittleness. Ιt 20 important for the oxide layer to be able to have a structure which eliminates or to a large extent counteracts mechanical stress concentrations implants inserted in the bone or equivalent, cf. the built-in stresses which can occur in connection with etched surfaces. Further demands and requirements are 25 that the process of incorporation of the implant in the bone or tissue can be improved. The invention solves this problem too.

In connection with the implant, it is possible 30 in some cases (i.e. in one embodiment) to use bonegrowth-initiating and bone-growth-stimulating agents and substances, for example those belonging to the superfamily TGF- $\beta$ . It is important to be able to apply the agent or the substance to or on the implant in a 35 technically simple and economically advantageous manner. The invention also solves this problem and proposes, through the novel oxide layer structure, a suitable depot function which can be used in long-term and optimal bone growth situations and incorporation

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functions for the implant in the bone or equivalent.

layers When producing thick oxide (for example, thicknesses of 5 - 20  $\mu$ m), it is important to able to offer technically reliable methods. economically advantageous The present invention also proposes methods satisfying conditions for production of oxide layers of the type in question. The method is based on the recognition that the electrolyte composition and/or the electrical voltages used can be of decisive importance.

#### SOLUTION

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The feature which can principally be regarded as characterizing a layer according to the invention is that it is designed with a channel network which gives the layer a substantial porosity, and that the channel network is designed with mouths which face towards the structure and whose respective cross-sectional areas, at the surface of the layer facing towards the structure, are substantially less than the respective extents of the channels in and down into the layer as seen from the said surface.

In a preferred embodiment, the channel network comprises contiquous channel branches which extend through at least the greater part of the layer as seen from the said surface and in to the transition to the body of the implant. The layer can be established on an undulating or uneven surface present on the implant from the start and having a high roughness value (for example 0.4 - 5  $\mu m$ ) for the purpose of increasing the layer volume. The channel network can also have channel branches which extend in directions which are different from the depth direction of the layer (or the radial direction of the implant). The layer has a thickness corrosion which gives substantial resistance relation to the previously proposed oxide arrangements. In one embodiment, the channel network can also be arranged with a mouth arrangement towards the bone or tissue structure, permitting increased

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release of bone growth substance from the channel network via the said mouths. The layer can be given an average thickness in accordance with the attached patent claims. Preferred values in respect of the surface area sizes of the mouths of the channel network, the total channel or pore volume in the layer, the surface roughness and the porosity are likewise indicated in the attached patent claims.

implant according to the invention can principally be regarded as being characterized by the fact that each layer present on the implant is designed with a channel network which gives the substantial porosity, and by the fact that the channel network is designed with mouths which face towards the structure and whose respective cross-sectional areas, at the surface of the layer facing towards the structure, are substantially less than the respective extents of the channels in and down into the layer as seen from the said surface.

20 In one embodiment, the implant can consist of a screw implant for application in bone, for example dentine. In a further embodiment, the oxide layer can form a depot for applied bone-growth-initiating or bone-growth-stimulating agent or substance. The agent or the substance can migrate from the depot to the bone tissue structure by means of concentration diffusion, which can be optimized by means of the channel network's mouth arrangement facing towards the bone or tissue structure. In a preferred embodiment, 30 the layer consists of or comprises a titanium oxide layer.

A method according to the invention starts out from anodic oxidation of the implant material question. The method can principally be characterized by the fact that diluted inorganic acids, organic acids and/or small quantities of hydrofluoric acid or hydrogen peroxide are added to the electrolytic composition which is used in the method, and by the fact that the energy source is chosen to operate with a

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voltage value of at least 150 volts. Thus, for example, voltage values in the range of 200 - 400 volts can be used.

In a preferred embodiment, the voltage varies at times for the same implant in order to create different channel or pore sizes within the same surface area or surface areas of the implant. In a further embodiment, different porosities or pore or channel characteristics can be obtained by means of position of the implant in the electrolyte being changed, together with the choice of the electrolyte composition and/or the voltage used. The thickness can also be varied by means of the said parameters.

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#### **ADVANTAGES**

By means of what has been proposed above, an improved implantation process is obtained, and, using the proposed oxide layer thicknesses at the upper end 20 of the proposed range, the invention goes against the which have hitherto been accepted technical field, thus opening up new avenues within the art. The concentration diffusion in conjunction with 25 the use of bone-growth-initiating and bone-growthstimulating substances can be considerably facilitated by the proposed channel make-up of the structure. The implant can be made commercially available with a finished oxide layer having the stated properties, and the novel method meets the conditions for economically advantageous layer production and implant production.

#### DESCRIPTION OF THE FIGURES

A presently proposed embodiment of a layer, an implant and a method according to the invention will be 35 described below with reference to the drawings, in which:

Figure 1 shows, in longitudinal section, illustrative embodiment of a titanium oxide layer

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produced on an implant body, the oxide layer starting from a relatively plane surface on the implant body,

Figure 2 shows, in longitudinal section, an example of the position of the oxide layer on an undulating surface or on a surface with a high degree of surface roughness,

Figure 3 shows a plan view, from outside, of an example of a mouth arrangement for a channel network arranged in the oxide layer,

Figure 4 shows, in vertical section and in diagrammatic form, a channel network for an oxide layer produced on an implant body, where the implant with associated oxide layer is applied in a partially shown bone and/or tissue structure in the human body, and in the oxide layer there is a channel network with a mouth arrangement facing towards the structure,

Figure 5 shows a side view of equipment for anodic oxidation of an implant,

Figure 6 shows, in diagram form, the voltage 20 and current functions used in association with the oxidation process, and

Figure 7 shows, in table form, parameters for building up different titanium oxide layers.

### 25 DETAILED EMBODIMENT

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In Figure 1, reference number 1 indicates parts of an implant body. As will be described below, the implant body has been treated in an oxidation function, resulting in an oxidation layer 2 having been formed on its outer surface. The oxidation layer can be built up on a surface structure which is relatively smooth from the outset, as has been indicated by 3 in Figure 1. The oxide layer 2 has a considerable thickness T. The layer can assume values of between 0.5 and 10  $\mu\text{m}$ , with the values preferably being towards the upper limit of the range. According to the invention, the invention will function primarily in the range of 2 - 10  $\mu\text{m}$ , although values as low as 0.5  $\mu\text{m}$  may be used in certain exceptional cases. The outer surface 2a of the oxide

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layer must have a surface roughness within the range of  $0.4-5~\mu m$ . According to what is described below, the oxide layer 2 has a high degree of porosity and encloses a channel network of specific type.

Figure 2 shows an example which differs from that in Figure 1 and where the oxide layer 2' has been built up on a surface structure 3' located on the implant 1' and having a relatively high degree of surface roughness, which has been obtained in a manner known per se upon production of the implant (e.g. by etching). The embodiment according to Figure 2 satisfies conditions for a relatively greater oxide layer volume than in the case according to Figure 1.

Figure 3 shows, from the outside of the oxide 15 layer 2'', mouths 3, 4 leading from the channel network mentioned above.

In Figures 1, 2 and 3, the scale is shown at the bottom right-hand corner, i.e. the size 10  $\mu m$  length in each figure.

In Figure 4, the implant is indicated by 1" 20 and the oxide layer produced on the implant indicated by 2'''. In Figure 4, a bone or tissue structure is indicated symbolically by 5. The structure can consist, for example, of a jaw bone in which the 25 implant can be screwed down into the equivalent. The implant can thus consist of or comprise titanium material, which means that the layer 2''' consists of a titanium oxide layer. The screw or the thread of the implant is not indicated in Figure 4, but 30 reference may be made to the already disclosed prior art and to known implants. The corresponding thread in the jaw bone 5 is not shown either, but here again reference may be made to the prior art. The oxide layer 2''' which is designed with the considerable thickness T', e.g. a thickness in the range of 5 - 25  $\mu m$ , is 35 provided with a channel network which is indicated symbolically by the arrow 6. In accordance with the above, the channel network has mouths or openings 3', 4'. The channel network branches down and/or in to the

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oxide layer, as seen from the outside 7 of the oxide layer. The channel network comprises different channel parts, for example 8, 9, 10. Channel routes can be established through the channel network which are made up of different channel parts and run from the outside 2a' of the layer 2''' and down or in towards a transition 11 between the implant and the oxide layer. Such a continuous channel formation is established with the channel parts or channel branches 12, 13, 14, 15 in the figure. A characteristic of the channel or pore formation according to the invention is that surface area or the diameter D of each mouth substantially less than the respective channel boundary or pore depth, for example a pore depth H. According to the above, the pore depth or channel depth can be significant and correspond, for example, to the said thickness T'. The channels can extend in the direction of depth of the oxide layer 2''' and/or in directions which are different than this direction, or in the radial direction R of the implant. The channel branches or the channel parts can be straight and/or curved, a curved channel branch having been indicated by 16 in Figure 4.

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It will be appreciated that such a channel 25 system can constitute a depot for substance which stimulates and/or initiates bone growth, and this has been symbolized by 17 in Figure 4. A substance thus introduced into the channel network can, by means of concentration diffusion, migrate out into the bone or 30 tissue structure, as has been symbolized by the arrow in Figure 4. Correspondingly, bone or tissue organisms can pass into the system in conjunction with the said diffusion. It will be appreciated that the mouths can be given different sizes and can create 35 conditions for bone growth with a specific penetration function in the mouth arrangement, contributing to the of incorporation of the implant in structure. The oxide layer of high porosity can be formed with 1 x  $10^7 - 1$  x  $10^{10}$  pores

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mouths)/cm². The diameter sizes can be chosen in the range of 0.1 - 10  $\mu$ m, and one and the same surface area of the oxide layer can have pores or channel mouths of different diameters or surface areas. A total volume for the channel network according to Figure 4 can be chosen in a range of 5 x 10<sup>-2</sup> and 10<sup>-5</sup> cm³.

The titanium oxide layers according to the above are preferably produced by so-called anodic oxidation, which is an electrochemical process. principle and the procedure for producing the layers in 10 question are described with reference to Figures 5 and 6. In Figure 5, a container is indicated by 20. A titanium anode is indicated by 21, and a porous meshed cathode is indicated by 22. A Teflon insulation of the titanium anode is indicated by 23, and the anodes 15 extend through a Teflon cover 24. A magnetic agitator 25 is also included. The attachments for anode and cathode are indicated by 21' and 22', respectively. The implant or the parts of the implant which are to be prepared are preferably mechanically worked by turning, 20 milling, polishing, etc. The implant or parts question comprise titanium surfaces which are to be treated in the electrochemical process. The implant or parts in question are mounted on a holder which is 25 immersed in a bath in the container consisting of an electrolyte 26. Those parts of the implant which are to be treated are masked by a liquid-tight protective sleeve or alternatively with a suitable lacquer which is arranged on the parts which are not to be treated. The implant or its said parts are 30 electrical contact, via the holder, with the attachment above the surface of the electrolyte. electrolyte, the said cathode 22 functions as counter-electrode. This counter-electrode is made of suitable material, for example Pt, gold or graphite. The counter-electrode is preferably mounted on the holder in such a way that the whole arrangement is jointly fixed in the electrolyte bath 26. The anodic oxidation is obtained by applying an electrical voltage

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between implant/implant part/implant parts and counterelectrode, whereupon the implant or its part or parts in question are given positive potential. The implant, implant part/implant parts, the counter electrode and the electrolyte constitute an electrochemical cell in which the implant or its respective part forms an anode. The difference in electrical potential between implant/implant part and counter-electrode gives rise stream of negatively (positive) electrolyte ions to the implant or implant (counter-electrode). If the electrolyte has been chosen suitably, the electrolyte reactions in the cell result in formation of an oxide layer on the implant or surface of the implant part. Since the electrode reactions also result in gas formation, the electrolyte should be stirred in a suitable manner, which is done with magnetic agitator 25, preventing gas bubbles from remaining on the electrode surfaces.

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The formation of the titanium oxide layer and its final properties are affected by a number of parameters in the process, e.g. the electrolyte's composition and temperature, the voltage and current applied, the electrode geometry and the treatment time. The way in which the desired layers are produced is described in more detail below. Examples are also given of how the process parameters affect various properties of the oxide layers and how the oxide thickness and porosity can be varied.

To achieve the desired layer properties, one starts, for example, from a mechanically worked surface which can be turned or polished. Cast and pressed implants or implant parts can also be used. The surface is cleaned in a suitable manner, for example by ultrasound cleaning in organic solvents in order to remove impurities from previous production stages. The cleaned implant or the cleaned implant part is secured in the said container, which is secured together with the counter-electrode on the holder. The arrangement can then be immersed in the electrolyte. The two

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electrodes are thereafter coupled to a voltage source (not shown) and an electrical voltage is applied, whereupon the process commences. The process is terminated, after the desired time, by interrupting the voltage application.

The electrical voltage can be applied different ways, cf. also Figure 6. In a galvanostatic process, the current is kept constant, the voltage being allowed to vary according to the resistance in the cell, whereas, in a potentiostatic process, the voltage instead is kept constant and the current is allowed to vary. The desired layers are preferably by using a combination of galvanostatic and potentiostatic control. Galvanostatic control is used in a first stage, the voltage being allowed to increase to a preset value. When this voltage value has been reached, the process changes over to potentiostatic control. On account of the resistance of the oxide layer which has been formed, the current drops in this state.

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Figure 6 shows the development of the current 27 and voltage 28 over time. The exact appearance of the curves depends on various process parameters and also reflects the formation of the oxide layer and its properties.

Up to a certain voltage, which is dependent on electrolyte, relatively thin oxide layers (< 0.2 µm) are obtained, where the oxide layer thickness is linearly dependent approximately the on voltage, and independent of treatment time after the maximum voltage has been reached. These layers are essentially closed, and only in exceptional circumstances do they have a partially open porosity. For most electrolytes, the critical voltage is about 100 volts.

To achieve the desired porous oxide layers, it is necessary to apply considerably higher voltages in excess of 150 volts, typically 200 - 400 volts, depending on electrolyte. At these voltages, the oxide

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thickness is no longer linearly dependent on the voltage, and, instead, considerably thicker layers can be produced. For certain electrolytes, the oxide thickness at these voltages is also dependent on the treatment time after the maximum voltage has been reached. Suitable electrolytes for achieving porous layers using this method are diluted inorganic acids (e.g. sulphuric acid, phosphoric acid, chromic acid) and/or diluted organic acids (e.g. acetic acid, citric acid), or mixtures of these.

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The implant which is treated in sulphuric acid has a surface with high density and open pores. Some 20% of the surface consists of pores or channels/ channel branches, with sizes (diameters) preferably in the range of 0.1 - 0.5 μm. The thickness of the layer can be 2 μm. The implant which is treated in phosphoric acid has a similar density of pores. The pore size distribution can differ considerably. In the case shown, pore sizes can be chosen preferably in the range of 0.3 - 0.5 μm, but a good number of larger pores (up to 1.5 μm) can also be present on the surface. The oxide thickness in this embodiment is 5 μm.

The table according to Figure 7 shows the structure of the oxide layer made with different process parameters in this method. The parameters shown are the electrolyte composition, voltage (volts), current (mA), time, pore diameter, pore density, porosity and oxide thickness.

The invention is not limited to the embodiment described above by way of example, but can be modified within the scope of the attached patent claims and the inventive concept.

#### PATENT CLAIMS

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- Layer (2) which can be arranged on an implant (1) 5 for bone or tissue structure (5) constitutes a boundary or barrier between the body of the implant and the structure for the purpose of increasing retention and which has, in this context, a substantial thickness (T), characterized in that the layer (2) is designed with a channel network (6) which 10 gives the layer a substantial porosity, and in that the channel network (6) is designed with mouths (3, which face towards the structure and whose respective cross-sectional diameters (D), at the surface (2a) of the layer facing towards the structure (5), 15 substantially less than the respective extents (H) of the channels in and down into the layer as seen from the said surface (2a').
- 2. Implant layer according to Patent Claim 1, characterized in that the channel network (6) comprises contiguous channel branches (12, 13, 14, 15) which extend through at least the greater part of the layer (2''') from the said surface (2a') and to the transition (11) from the layer to the body (1'') of the implant.
  - 3. Implant layer according to Patent Claim 1 or 2, characterized in that the channel network (6) has channel branches (10) which extend in directions which are different than the depth direction of the layer or the radial direction of the implant.
  - 4. Implant layer according to Patent Claim 1, 2 or 3, characterized in that it is established on an undulating or uneven surface (3') present on the implant from the start and having a high roughness value, for example 0.4 5  $\mu m$ , for the purpose of increasing the layer volume.
  - 5. Implant layer according to any of the preceding patent claims, characterized in that it has a thickness (T) which gives a substantial corrosion resistance for

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the implant as a whole.

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Implant layer according to any of the preceding 6. characterized in that the channel patent claims, network (6) is arranged with a mouth arrangement (3',

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- 4') towards the bone ortissue structure permitting increased bone growth penetration into the channel at the said mouths (compared to conventional oxide layers).
- 7. Implant layer according to any of the preceding patent claims, characterized in that the layer has an 10 average thickness in the range of 0.5 - 20  $\mu m$ , preferably in the range of 2 - 20  $\mu m$ .
  - Implant layer according to any of the preceding patent claims, characterized in that the oxide layer has a surface roughness, at its outer surface, in the range of 0.4 - 5  $\mu$ m.
  - Implant layer according to any of the preceding patent claims, characterized in that the oxide layer has a high degree of porosity, with a number of  $1 \times 10^7$  $-1 \times 10^{10} \text{ pores/cm}^3$ .
  - Implant layer according to any of the preceding patent claims, characterized in that each surface has pores or channel mouth areas with diameters or surface area sizes in the range of 0.1 - 10  $\mu m$ , and/or in that the total channel network or pore volume lies in a range of 5 x  $10^{-2}$  and  $10^{-5}$  cm<sup>3</sup>.
  - Implant layer according to any of the preceding patent claims, characterized in that the layer consists of or comprises a titanium oxide layer.
- 30 12. Implant layer according to any of the preceding patent claims, characterized in that the consists of a screw implant for application in the jaw bone.
- Implant layer according to any of the preceding 35 patent claims, characterized in that the layer forms a for applied bone-growth-initiating or bonegrowth-stimulating agent or substance (17).
  - 14. Implant layer according to any of the preceding patent claims, characterized in that the agent or the

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substance migrates from the depot to the bone or tissue structure (5) by means of concentration diffusion.

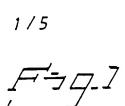
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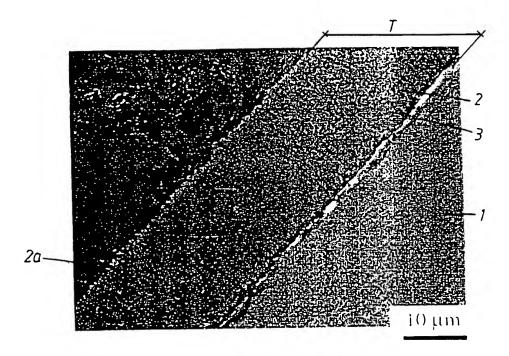
- . 15. Implant (1) for bone or tissue structure (5) and comprising one or more layers (2) which constitute a boundary (or boundaries) between the body (1) of the implant and the structure (5) for the purpose of increasing retention and which each have, in this context, a substantial thickness, characterized in that each layer is designed with a channel network (6) which gives the layer (2) a substantial porosity, and in that 10 the channel network (6) is designed with mouths (3, 4) which face towards the structure and whose respective cross-sectional diameters (D), at the surface of the layer facing towards the structure, are substantially less than the respective extents (H) of the channels in 15 and down into the layer as seen from the said surface (2a').
- Method for producing, by anodic oxidation, on 16. implant comprising or consisting of titanium, 20 relatively thick oxide layers (2) on one or more titanium surfaces which are intended to be placed against or arranged next to one or more tissue and/or growth areas (5), where at least the part or parts supporting the said surface or surfaces are 25 prepared and immersed in electrolyte (26) implant is brought into contact with an electrical energy source above the electrolyte surface and the oxidation process is established by also connecting to the energy source a counter-electrode arranged in the 30 electrolyte (26), characterized in that diluted inorganic acids, diluted organic acids and/or small quantities of hydrofluoric acids or hydrogen peroxide are added to the electrolytic composition, and in that the energy source is chosen to operate with voltage values of at least 150 volts, for example with voltage 35 values in the range of 200 - 400 volts.
  - 17. Method according to Patent Claim 12, characterized in that the voltage (28) is varied at times for the same implant in order to create different

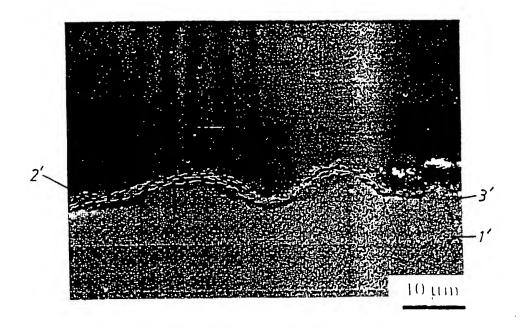
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channel or pore sizes within the same surface area.

18. Method according to Patent Claim 16 or 17, characterized in that the position of the implant in the electrolyte is changed together with the composition of the electrolyte (26) and/or the voltage (28) in order to create different oxide thicknesses (T, T') and/or areas of different porosity or pore or channel characteristics.



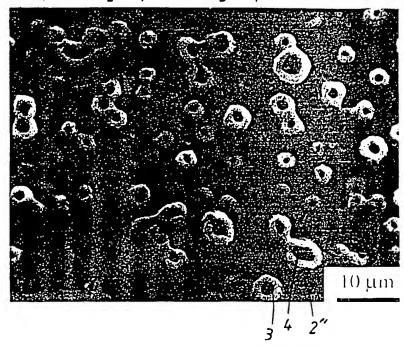




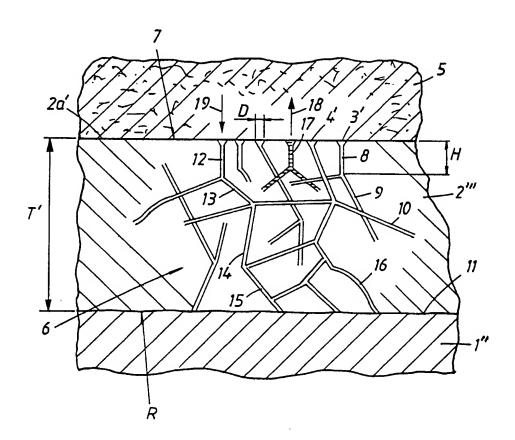
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N42, 0.15 M H2 SO4 + 0.25 M H3 PO4, 300 V, 200 mA. 300 s

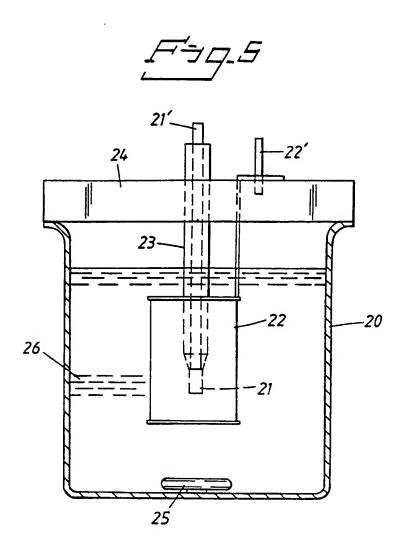


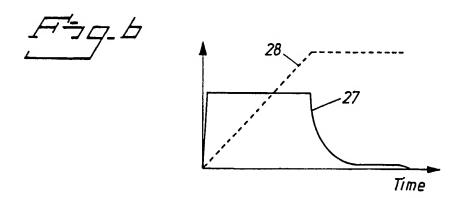




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Electrolyte	n	н	Time	Pore	Pore	Porosity	Oxide
	(3	(mA)	(8)	diam.	density	(%)	thickness
				(mm)	$(10^8/cm^2)$		(mm)
0.35M H <sub>2</sub> SO <sub>4</sub>	250	300	400	n.a.			9.2-13.5
0.35M H2SO4	250	800	300	n.a.			19.1-21.3
1.0M H2SO4	200	200	400	n.a.			5.8-6.5
0.35M H2SO4	200	200		0.28-	0.45	5.65	3.5-7.0
+160 min.				0.92			
0.35M H2SO4	200	200	300	-90.0	2.48	6.47	2.2-2.8
etched				0.43			
0.15M H <sub>2</sub> SO4+	300	200	300	0.31-	0.078	4.16	2.9-6.5
				2.27			
0.25M H2SO4+	300	200	300	0.31-	0.080	7.84	3.6-6.5
				2.65			
0.35M H2SO4+	300	1400	300	0.31-	090.0	10.69	3.6-11.0
				4 06			

## INTERNATIONAL SEARCH REPORT

International application No.

# PCT/SE 00/01026

A. CLASSIFICATION OF SUBJECT MATTER		
IPC7: A61C 8/00, A61L 27/04, A61L 27/54 According to International Patent Classification (IPC) or to both n	ational classification and IPC	
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed to	y classification symbols)	
IPC7: A61C, A61L		
Documentation searched other than minimum documentation to the	e extent that such documents are included i	in the fields searched
SE,DK,FI,NO classes as above  Electronic data base consulted during the international search (name	o of data have and where prominable searce	h terme used)
Electronic data base consulted during the international search (hair	e of data oast and, where praedecist, seaso	n anni useu)
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category* Citation of document, with indication, where ap	propriate, of the relevant passages	Relevant to claim No.
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A US 5354390 A (KÁROLY HASZMANN E 11 October 1994 (11.10.94)	T AL),	1-18
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Further documents are listed in the continuation of Bo	x C. X See patent family annex	<u>.                                    </u>
Special categories of cited documents:	"T" later document published after the int date and not in conflict with the appli	ernational filing date or priority cation but cited to understand
"A" document defining the general state of the art which is not considered to be of particular relevance	the principle or theory underlying the	invention
"E" erlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is	"X" document of particular relevance: the considered novel or cannot be conside step when the document is taken alon	red to involve an inventive
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means "P" document published prior to the international filing date but later that the priority date claimed	combined with one or more other such being obvious to a person skilled in the same patent of the same patent	ne art
Date of the actual completion of the international search	Date of mailing of the international	search report
10 50-4 2000	2 0 -09- 200	)
18 Sept 2000 Name and mailing address of the ISA/	Authorized officer	
Swedish Patent Office		
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